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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/042,583 | 03/17/1998 | JIAN NI | PF366 | 5224 |

28730 7590 04/12/2005

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| EXAMINER | |
|---|---|
| KAUFMAN, CLAIRE M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/042,583 | NI ET AL. | |
| | Examiner | Art Unit | |
| | Claire M. Kaufman | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *287-322, 324, 326-361, 374-403, 416-432, 434-442, 446-491, 507-517, 553-596, 598-607, and 623-632* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *See Continuation Sheet* is/are allowed.

6)☐ Claim(s) *300-304,307-315,340-350,374,375,377-385,416,417,419-427 and 446-491* is/are rejected.

7)☐ Claim(s) *305,306,316-318,376,386-388,418 and 428-430* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims allowed are 287-299,319-322,324,326-339,351-361,389-403,431,432,434-442,507-517,553-596,598-607 and 623-632.

## DETAILED ACTION

### *Response to Arguments*

The rejections of the previous Office action are withdrawn in view of the amendment to the claims and submission of the terminal disclaimer of 11/8/04. However, new rejections appear below.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 446-491 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cDNA clone in ATCC Deposit No. 97920 and it does not appear to be a readily available material. Even though the cDNA clone was deposited as ATCC Deposit No. 97920 on March 7, 1997 (*e.g.*, p. 7, beginning line 20) the full requirements for deposit have not been met so as to satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions

imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claims 300-304, 307-315, 340-350, 374, 375, 377-385, 416, 417, 419-427, 459-461 and 464-472 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claims 300, 340, 374, 416 and 459 are drawn to a polynucleotide comprising a first nucleic acid at least 90% identical to a particular portion of SEQ ID NO:2, wherein the first nucleic acid hybridizes under stringent conditions (listed in the claims) to nucleotides 130, 133 or 284 to 1362 of SEQ ID NO:1. There is no functional limitation in the claims. The hybridization conditions serve only to define structure. The recitation of % identity defines limitations of size (see paragraph bridging pages 14-15 of the specification) relative to a second nucleic acid. It also defines structure, for example, a first nucleic acid 90% identical to a second

nucleic acid encoding amino acids 273-340 of SEQ ID NO:2 allows the second encoding sequence to cover all degenerate sequences, resulting in a myriad of possible sequences for the first nucleic acid. The ability to hybridize to a particular nucleic acid sequence or, to take it a step further, to be used as a probe for a particular nucleic acid does not enable the skilled artisan to use the claimed polynucleotide for several reasons. First, one of skill in the art would not recognize using a probe that is not identical to the sequence of the nucleic acid being probed for if there was a better alternative. Second, there is no practical function associated with the claimed polynucleotide so that one skilled in the art would know how to use it. The specification provides no guidance or examples of how to use non-identical nucleic acids unless they encode particular disclosed regions of SEQ ID NO:2 or have a function of DR5 (*i.e.*, induction of apoptosis or binding of TRAIL) or can function within SEQ ID NO:2 as described, for example, in claim 376.

Claims 300-304, 307-315, 340-350, 374, 375, 377-385, 416, 417, 419-427 and 459-461, 464-472 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 300, 340, 374, 416 and 459 are drawn to a polynucleotide comprising a first nucleic acid at least 90% identical to a second nucleic acid encoding a particular portion of SEQ ID NO:2, wherein the first nucleic acid hybridizes under stringent conditions (listed in the claims) to nucleotides 130, 133 or 284 to 1362 of SEQ ID NO:1. The claims do not require that the polynucleotide to possess any particular biological activity, particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the

claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Which polynucleotides of the genus comprising the required sequence are part of the invention has not been set forth.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides comprising the nucleic acid sequence set forth in SEQ ID NO:1 or disclosed fragments or encoding fragments with function, but not the full breadth of the claims meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. On the IDS file 11/8/04, Applicants cite three US Pre-Grant Publications of Holtzman (AI1-AK1). These applications disclose Tango 63 and splice variants thereof, which are the same as or share high identity with to SEQ ID NO:2 of the instant application. However, the earliest priority applications of Holtzman to disclose Tango 63 are 09/757,421, filed 1/10/01, and 08/843,652, filed 4/16/97; and, therefore, none of the Holtzman documents are available as prior art.

***Conclusion***

Claims 287-299, 319-322, 324, 326-339, 351-361, 389-403, 431, 432, 434-442, 507-517, 553-596, 598-607 and 623-632 are allowable.

Claims 305, 306, 316-318, 376, 386-388, 418 and 428-430 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

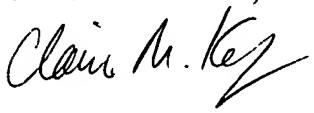
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

April 4, 2005

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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